SONICATOR PLUS® 930, MODEL ME 930
510(K) SUMMARY STATEMENT (K013192)

OCT 1 7 2001

Submitter's Name: Mettler Electronics Corp.
Address: 1333 South Claudina Street
Anaheim, CA 92805

Telephone: 714-533-2221

Contact: Robert E. Fleming
Director of Operations

Date Prepared: October 1, 2001

Proposed Device Name:

a. TRADE NAME: Sonicator® Plus 930, Model ME 930
b. CLASSIFICATION NAME: Ultrasound and Muscle Stimulator
c. COMMON NAME: Combination ultrasound and Muscle Stimulator

Predicate Device:

a. TRADE NAME: Sonicator® Plus 992, Model ME 992
b. 510(k) Number: K984142

Description of Proposed Device:

The Sonicator Plus 930 is a two-channel combination unit for therapeutic ultrasound and muscle stimulation. The microprocessor controlled Sonicator Plus 930 provides pre-modulated medium frequency and symmetrical biphasic waveforms with enhanced reliability and ease of use. In addition the Sonicator Plus 930 offers 1 and 3 MHz ultrasound using a variety of interchangeable applicators.

The two-channel Sonicator Plus 930 allows the clinician to utilize up to two different waveforms using two channels simultaneously. The clinician can choose between several different amplitude modulation options such as the surge, reciprocation and amplitude modulation *(interferential only, vector rotation)*. The interferential and pre-modulated modes offer frequency modulation as well as a static frequency option.

The membrane panel provides both tactile and audio feedback when buttons are pressed. Blinking LED's guide the operator through the easy setup routine. The new Treatment Status Indicator shows the operator which stimulation waveform has been chosen for treatment. The status display moves when treatment output is active.

Large, soft-touch control knobs make adjusting power for ultrasound and stimulation easy to accomplish with no guesswork involved. Two LED output displays allow the clinician to monitor two channels simultaneously for two channel combination treatment protocols. These also allow the operator to adjust both channels of an interferential protocol simultaneously while monitoring the current.

The Sonicator Plus 930 can provide electrical stimulation only, ultrasound only and combination therapy with the pre-modulated, biphasic and medium frequency waveforms

Proposed Device Intended Use Statement:

510(k) Number: K013192

Device Name: Sonicator® Plus 930, Model ME 930

Proposed Device Indications For Use (same as those for predicate device):

Therapeutic Ultrasound

1. Pain relief
2. Reduction of muscle spasm
3. Localized increase in blood flow
4. Increase range of motion of contracted joints using heat and stretch techniques.

Neuromuscular Stimulation

1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain (Interferential and Pre-modulated waveforms)
2. Temporary relaxation of muscle spasm (all waveforms)
3. Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles (all waveforms)
4. Increase of blood flow in the treatment area (all waveforms)
5. Prevention or retardation of disuse atrophy in post-injury type conditions (all waveforms)
6. Muscle re-education (all waveforms)
7. Maintaining or increasing range of motion (all waveforms)

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Comparison of Technological Characteristics Between Proposed and Predicate Devices:

Pain Management

510 K #	K013192	K984142
Device Name	**Sonicator Plus 930**	**Sonicator Plus 992**
Manufacturer	**Mettler Electronics**	**Mettler Electronics**
Power Source	AC Line	AC Line
Number of output modes	4	6
Channel(s)	2	2
Synchronous	1 & 2	1 & 2
Reciprocal	1 & 2	1 & 2
Other	Yes	Yes
Computerized	No	No
Software provided	N/A	N/A
Constant current	Yes	Yes
Constant voltage	No	No
Max output current (mA)	0–65 ±10% mA RMS, max., 1 Kohm load, Interferential mode	0–65 ±10% mA RMS, max., 1 Kohm load, Interferential mode
	0–50 ±10% mA RMS, max., 1 Kohm load, premodulated mode	0–50 ±10% mA RMS, max., 1 Kohm load, premodulated mode
		10-990 ±10 μA peak, 1 Kohm load, microamp mode
Max output voltage (V)	0–65 ±10% volts RMS, 1 Kohm load, Interferential mode	0–65 ±10% volts RMS, 1 Kohm load, Interferential mode
	0–50 ±10% volts RMS premodulated mode	0–50 ±10% volts RMS premodulated mode
		1.0 ±10% volt peak, 1 Kohm load, microcurrent mode
Waveforms & Channels		
All Channels	Premodulated	Premodulated
Channel 1 & 2	Interferential	Interferential
Channel 1	Combination Therapy and all others	High Volt and Combination Therapy and all others except microcurrent
Channel 2	All	Microcurrent and all others except high volt
Output displays	Two simultaneously, amber channel active indicators	Two simultaneously, amber channel active indicators

	channel active indicators	channel active indicators
Channel isolation	Yes	Yes
Line current isolation	Yes	Yes
Automatic overload trip	Yes	Yes
Automatic over current trip	Yes	Yes
Current/Voltage level	70 mA RMS, interferential mode	70 mA RMS, interferential mode
	55 mA RMS, premodulated mode	55 mA RMS, premodulated mode
		110 mA peak, microcurrent
Automatic no load trip	Yes	Yes
Patient override	None	None
control method	On/Off or Hold	On/Off or Hold
Max leakage current (µA)		
Chassis	<100	<100
Electrodes	<100	<100
Indicator display		
Unit functioning	Yes	Yes
Low battery indicator	N/A	N/A
Standards		
UL 544	No	No
UL 2601-1-UL	Yes	Yes
CUL	No	No
CSA C22.2 NO 601.1-M90	Yes	Yes
IEC60601-2-10	Yes	Yes
EN–55011 (CISPR–11)	Yes	Yes
MDD 93/42/EEC, Annex II	Yes	Yes
Timer settings	1–60 minutes ±5%	1–60 minutes ±5%
Automatic shut-off	Yes	Yes
Weight (lbs.)	10	10
Dimensions (in.)		
H x W x L	6 in (H) x 12 in (W) x 12 in (D)	5 (H) x 14.5 (W) x 10 (D)

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Housing materials	Aluminum chassis with an ABS cover	Aluminum
Construction	Folded into a box shape and seams welded & ground flush and a stylized ABS cover screwed onto metal box.	Stamped in a flat pattern, embossed, folded into a box shape and seams welded & ground flush
II. Monophasic current		
type	N/A	Monophasic and biphasic, microcurrent
Shape		Square, (Microcurrent)
Net Charge		Positive or negative or neutral depending on the polarity, microcurrent
Max phase rise time		Less than 1μs
Max phase decay time		Less than 100 μs
Phase duration range		1-1000, ±10% ms, microcurrent mode
Interpulse interval		N/A, microcurrent mode
Frequency range		0.5 to 500 Hz, ±0.5 Hz or ±5%, whichever is greater, microcurrent mode
Maximum current density		49 μA/cm², microcurrent mode
III. Alternating Current		
Type	Biphasic	Biphasic
Shape	Sinusoidal, (Interferential, Premodulated modes)	Sinusoidal, (Interferential, Premodulated modes)
Symmetry	Symmetrical	Symmetrical
	Balanced	Balanced
Net charge	Zero	Zero
method	Balanced Waveform	Balanced Waveform
Max phase rise time	62.5 μs (Interferential and Premodulated)	62.5 μs (Interferential and Premodulated)
Max phase decay time	62.5 μs (Interferential and Premodulated)	62.5 μs (Interferential and Premodulated)
Phase duration range		
interferential	118–125 μs ±1%	118–125 μs ±1%
premodulated	118–125 μs ±1%	118–125 μs ±1%
Interphase interval	N/A	N/A

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Frequency range	4000–4250 Hz ±1%, (Interferential and Premodulated modes)	4000–4250 Hz ±1%, (Interferential and Premodulated modes)
Beat Frequency (pps)	1–250 ±2 Hz or 10%, whichever is greater	1–250 ±2 Hz or 10%, whichever is greater
Interference Pattern	Yes	Yes
Maximum Current Density	3.52 mA/cm², interferential 2.64 mA/cm², premodulated	3.52 mA/cm², interferential 2.64 mA/cm², premodulated
Maximum Phase Charge (u Coulombs)		
500 OHMS (Interferential)	8.9	8.9
2K OHMS	7.0	7.0
10K OHMS	1.5	1.5
Formula	q = I x t	q = I x t
500 OHMS (Premodulated)	69.5	69.5
2K OHMS	4.7	4.7
10K OHMS	1.0	1.0
Formula	q = I x t	q = I x t
500 OHMS (Microcurrent)	N/A	1000
2K OHMS	960	960
10K OHMS	610	610
Formula	q=1 x t	q=1 x t
Amplitude Modulation Options		
Reciprocal (Premodulated)	2–240 s ±10%	2–240 s ±10% or combine with Surge for different On/Off times

Surge (Premodulated)		
Up Ramp	3 s ± 0.5 s (all)	3 s ± 0.5 s (all)
Down Ramp	2 s ± 0.5 s (all)	2 s ± 0.5 s (all)
Frequency	All Selectable Frequencies	All Selectable Frequencies
On Times	5 s, 10 s	10 s or 1–240 ±10% s
Off Times	5 s, 10 s, 30 s or 50 s	10 s, 20 s, 30 s , 40 s, 50 s, 60 s or 1–240 s ±10%
Amplitude Modulation, Vector (Interferential)		
Description	-50% amplitude modulation in anti phase	-50% amplitude modulation in anti phase
Modulation Period	8 s ± 1 s modulation period	8 s ± 1 s modulation period
Frequency Modulation Options		
Interferential or Premodulated	1–15 Hz ± 2 Hz or 10% whichever is greater	1–15 Hz ± 2 Hz or 10% whichever is greater
	80–150 Hz ± 2 Hz or 10% whichever is greater	80–150 Hz ± 2 Hz or 10% whichever is greater
	1–150 Hz ± 2 Hz or 10% whichever is greater	1–150 Hz ± 2 Hz or 10% whichever is greater
	xx–xx Hz ± 2 Hz or 10% whichever is greater, *xx = any value from 1 to 250 Hz*	xx–xx Hz ± 2 Hz or 10% whichever is greater, *xx = any value from 1 to 250 Hz*
Modulation Options		
a) May be selected independently or together	Yes	Yes
b) Simultaneously for each channel pair	Yes	Yes
c) Independent controls for each channel	Yes	Yes

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Comparison of Technological Characteristics Between Proposed and Predicate Devices (continued):

Neuromuscular Stimulation

510 K #	K013912	K984142
Device Name	**Sonicator Plus 930**	**Sonicator Plus 992**
Manufacturer	**Mettler Electronics**	**Mettler Electronics**
Power Source	AC Line	AC Line
Number Of Output Modes	3	6
Channel(S)	2	2
Synchronous	1 & 2	1 & 2
Reciprocal	1 & 2	1 & 2
Other	Yes	Yes
Computerized	No	No
Software Provided	N/A	N/A
Constant Current	Yes	Yes
Constant Voltage	No	No
Max Output Current (mA)	0–65 ±10% mA RMS, max., 1 Kohm load, Interferential mode 0–50 ±10% mA RMS, max., 1 Kohm load, premodulated and medium frequency modes	0–65 ±10% mA RMS, max., 1 Kohm load, Interferential mode 0–50 ±10% mA RMS, max., 1 Kohm load, premodulated and medium frequency modes 0 –99 ±10% mA peak, max., 1 Kohm load, biphasic mode 0-2500 ±10% mA peak, max., 1 Kohm, high volt mode 10-990 ±10 µA peak, 1 Kohm load, microamp mode
Max Output Voltage (V)	0–65 ±10% volts RMS, 1 Kohm load, Interferential mode 0–50 ±10% volts RMS premodulated mode and medium frequency modes	0–65 ±10% volts RMS, 1 Kohm load, Interferential mode 0–50 ±10% volts RMS premodulated mode and medium frequency modes 99 ±10% volts peak, 1 Kohm load, biphasic mode 0-500 ±10% volts peak, 1 Kohm load, high volt mode 1.0 ±10% volt peak, 1 Kohm load, microcurrent mode

Waveforms & Channels		
All Channels	Premodulated, Medium Frequency	Premodulated, Medium Frequency, Biphasic
Channel 1 & 2	Interferential	Interferential
Channel 1	Combination Therapy and all others	High Volt and Combination Therapy and all others except microcurrent
Channel 2	All	Microcurrent and all others except high volt
Output Displays	Two simultaneously, amber channel active indicators	Two simultaneously, amber channel active indicators
Channel Isolation	Yes	Yes
Line Current Isolation	Yes	Yes
Automatic Overload Trip	Yes	Yes
Automatic Over Current Trip	Yes	Yes
Current/Voltage Level	70 mA RMS, interferential mode	70 mA RMS, interferential mode
	55 mA RMS, premodulated and medium frequency modes	55 mA RMS, premodulated and medium frequency modes
		110 mA peak, biphasic
		N/A, high volt and microcurrent modes
Automatic No Load Trip	Yes	Yes
Patient Override	None	None
Control Method	On/Off or Hold	On/Off or Hold
Max Leakage Current (µA)		
Chassis	<100	<100
Electrodes	<100	<100
Indicator Display		
Unit Functioning	Yes	Yes
Low Battery Indicator	N/A	N/A
Standards		
UL 544	No	No
UL 2601-1-UL	Yes	Yes
CUL	No	No
CSA C22.2 NO 601.1-M90	Yes	Yes

IEC60601-2-10	Yes	Yes
EN–55011 (CISPR–11)	Yes	Yes
MDD 93/42/EEC, Annex II	Yes	Yes
Timer Settings	1–60 minutes ±5%	1–60 minutes ±5%
Automatic Shut Off	Yes	Yes
Weight (lbs.)	9	10
DIMENSIONS (in.)		
H x W x L	6 in (H) x 12 in (W) x 12 In (D)	5 (H) x 14.5 (W) x 10 (D)
Housing Materials	Aluminum chassis with an ABS cover	Aluminum
Construction	Folded into a box shape and seams welded & ground flush and a stylized ABS cover screwed onto metal box.	Stamped in a flat pattern, embossed and folded into a box shape and seams welded & ground flush
II. Monophasic Current	N/A	
Type		Monophasic, high volt
		Monophasic and biphasic, microcurrent
Shape		Twin spikes, (high volt)
		Square, (Microcurrent)
Net Charge		Positive or Negative depending on the polarity, high volt
		Positive or negative or neutral depending on the polarity, Microcurrent
Max Phase Rise Time		Less than 1μs
Max Phase Decay Time		Less than 100 μs
Phase Duration Range		10 μs, ±5 μs at 50% amplitude, high volt mode
		1-1000, ±10% ms, microcurrent mode
Interpulse Interval		75 μs, ±25 μs at 50% amplitude, high volt
		N/A, microcurrent mode
Frequency Range		1-120 Hz, ±1 Hz or ±5%, whichever is greater, high volt mode
		0.5 to 500 Hz, ±0.5 Hz or ±5%, whichever is greater, microcurrent mode
Maximum Current Density		0.088 mA/cm², high volt mode
		49 μA/cm², microcurrent mode

III. Alternating Current

Type	Biphasic	Biphasic
Shape	Sinusoidal, (Interferential, Premodulated and Medium Frequency)	Sinusoidal, (Interferential, Premodulated and Medium Frequency)
		Square, (Biphasic)
Symmetry	Symmetrical	Symmetrical
	Balanced	Balanced
Net Charge	Zero	Zero
Method	Balanced Waveform	Balanced Waveform
Max Phase Rise Time	62.5 µs (Interferential and Premodulated)	62.5 µs (Interferential and Premodulated)
	100 µs (Medium Frequency)	100 µs (Medium Frequency)
		Less than 10 µs (Biphasic)
Max Phase Decay Time	62.5 µs (Interferential and Premodulated)	62.5 µs (Interferential and Premodulated)
	100 µs (Medium Frequency)	100 µs (Medium Frequency)
		Less than 5 µs (Biphasic)
Phase Duration Range		
Interferential	118–125 µs ±1%	118–125 µs ±1%
Premodulated	118–125 µs ±1%	118–125 µs ±1%
Medium Frequency	200 ±2% µs	200 ±2% µs
Biphasic	N/A	50–300 ±10% µs
Interphase Interval	N/A	N/A
Frequency Range	4000–4250 Hz ±1%, (Interferential and Premodulated modes)	4000–4250 Hz ±1%, (Interferential and Premodulated modes)
	2500 Hz ±2% (Medium Frequency mode)	2500 Hz ±2% (Medium Frequency mode)
		1–120 ±1 Hz or ±5% whichever is greater, (Biphasic mode)
Beat Frequency (pps)	1–250 ±2 Hz or 10%, whichever is greater	1–250 ±2 Hz or 10%, whichever is greater
Burst Mode	Yes (Medium Frequency—10 ms On/Off, 50 Hz)	Yes (Medium Frequency—10 ms On/Off, 50 Hz)
Interference Pattern	Yes	Yes

Maximum Current Density	3.52 mA/cm², interferential 2.64 mA/cm², premodulated and medium frequency	3.52 mA/cm², interferential 2.64 mA/cm², premodulated and medium frequency 0.176 mA/cm², biphasic
Maximum Phase Charge (u Coulombs)		
500 OHMS (Interferential)	8.9	8.9
2K OHMS	7.0	7.0
10K OHMS	1.5	1.5
Formula	q = I x t	q = I x t
500 OHMS (Premodulated)	69.5	69.5
2K OHMS	4.7	4.7
10K OHMS	1.0	1.0
Formula	q = I x t	q = I x t
500 OHMS (Medium Frequency)	16.0	16.0
2K OHMS	11.4	11.4
10K OHMS	2.5	2.5
Formula	q = I x t	q = I x t
500 OHMS (Biphasic)	N/A	29.8
2K OHMS		27.9
10K OHMS		6.1
FORMULA		q = I x t
500 OHMS (High Volt)	N/A	14.9
2K OHMS		3.9
10K OHMS		0.8
Formula		q=1 x t
500 OHMS (Microcurrent)	N/A	1000

2K OHMS		960
10K OHMS		610
Formula		q=1 x t
Amplitude Modulation Options		
Reciprocal (Premodulated, Biphasic, Medium Frequency)	2–240 s ±10%	2–240 s ±10% or combine with Surge for different On/Off times
Surge (Premodulated, Biphasic, Medium Frequency, High Volt)		
Up Ramp	3 s ± 0.5 s (all)	3 s ± 0.5 s (all)
Down Ramp	2 s ± 0.5 s (all)	2 s ± 0.5 s (all)
Frequency	All Selectable Frequencies	All Selectable Frequencies
On Times	5 s, 10 s	10 s or 1–240 ±10% s
Off Times	5 s, 10 s, 30 s or 50 s,	10 s, 20 s, 30 s , 40 s, 50 s, 60 s or 1–240 s ±10%
Amplitude Modulation, Vector (Interferential)		
Description	-50% amplitude modulation in anti phase	-50% amplitude modulation in anti phase
Modulation Period	8 s ± 1 s modulation period	8 s ± 1 s modulation period
Frequency Modulation Options		
Interferential or Premodulated	1–15 Hz ± 2 Hz or 10% whichever is greater	1–15 Hz ± 2 Hz or 10% whichever is greater
	80–150 Hz ± 2 Hz or 10% whichever is greater	80–150 Hz ± 2 Hz or 10% whichever is greater
	1–150 Hz ± 2 Hz or 10% whichever is greater	1–150 Hz ± 2 Hz or 10% whichever is greater
	xx–xx Hz ± 2 Hz or 10% whichever is greater, *xx = any value from 1 to 250 Hz*	xx–xx Hz ± 2 Hz or 10% whichever is greater, *xx = any value from 1 to 250 Hz*

Modulation Options		
a) May be selected independently or together	Yes	Yes
b) Simultaneously for each channel pair	Yes	Yes
c) Independent controls for each channel	Yes	Yes

Therapeutic Ultrasound

510 K #	**K013192**	**K984142**
Device Name	**Sonicator® Plus 930**	**Sonicator Plus 992**
Manufacturer	**Mettler Electronics**	**Mettler Electronics**
Power Source	AC Line	AC Line
Standards		
UL 544	No	No
UL 2601-1-UL	Yes	Yes
CUL	No	No
CSA C22.2 NO 601.1-M90	Yes	Yes
IEC60601-2-5	Yes	Yes
FCC Part 15–B	Yes	Yes
EN–55011 (CISPR–11)	Yes	Yes
FDA, 21 CFR 1050.10	Yes	Yes
MDD 93/42/EEC, Annex II	Yes	Yes
Timer Accuracy:	±0.5 minutes for times less than 5 minutes ±10% for times from 5 to 10 minutes ±1.0 minute for times grater that 10 minutes	±0.5 minutes for times less than 5 minutes ±10% for times from 5 to 10 minutes ±1.0 minute for times grater that 10 minutes
Maximum Treatment Time:	30 minutes–ultrasound or combination therapy	30 minutes–ultrasound or combination therapy

SONICATOR PLUS® 930, MODEL ME 930
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Ultrasonic Generator Specifications		
Frequency	1.0 MHz ±5% 3.2 MHz ±5%	1.0 MHz ±5% 3.2 MHz ±5% 3.3 MHz ±5%
Modes	Continuous Pulsed—20% duty cycle	Continuous Pulsed—20% duty cycle Pulsed—50% duty cycle
Pulse Repetition Rate	100 Hz ±20%	100 Hz ±20%
Pulse Duration	2 msec ±20%, 20% duty cycle	2 msec ±20%, 20% duty cycle 5 msec ±20%, 50% duty cycle
Temporal Peak/ average intensity ratio	5:1 ±20%, 20% duty cycle	5:1 ±20%, 20% duty cycle 2:1 ±20%, 50% duty cycle
Maximum output power	11 W with a 5 cm^2 applicator, (ME 7513)	22 W with a 10 cm^2 applicator, (ME 7310) 11 W with a 5 cm^2 applicator, (ME 7513) 2.2 W with a 1 cm^2 applicator (ME 7331)
Maximum intensity	2.2 W/cm^2	2.2 W/cm^2 with all applicators
Indication accuracy	±20% (for any level above 10% of maximum)	±20% (for any level above 10% of maximum)
Ultrasonic Applicator Specifications		
Piezoelectric discs	The output transducer utilizes a barium titanate disc with a specially coated face.	The output transducer utilizes a barium titanate disc with a specially coated face.
Applicator Part Number		
ME 7310	N/A	
Frequency		1 MHz ±5%
Effective Radiating Area		10 cm^2±10%
ME 7331	N/A	
Frequency		3.3 MHz ±5%
Effective Radiating Area		1 cm^2±10%

ME 7513		
Frequency	1 or 3.2 MHz ±5%	1 or 3.2 MHz ±5%
Effective Radiating Area	5 cm^2±10%	5 cm^2±10%
Maximum Beam Non–Uniformity Ratio	6:1	6:1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 7 2001

Mr. Robert E. Fleming
Director of Operations
Mettler Electronics Corporation
1333 South Claudina Street
Anaheim, California 92805

Re: K013192
Trade/Device Name: Sonicator® Plus 930, Model ME 930
Regulation Number: 890.5300, 890.5850, 882.5890
Regulation Name: Ultrasonic diathermy
Powered muscle stimulator
Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: IMI, IPF, GZJ, LIH
Dated: September 21, 2001
Received: September 25, 2001

Dear Mr. Fleming:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT
SONICATOR PLUS 930, ME 930

510(k) Number: K013192

Device Name: Sonicator® Plus 930, Model ME 930

Proposed Device Indications For Use (same as those for predicate device):

Therapeutic Ultrasound

1. Pain relief
2. Reduction of muscle spasm
3. Localized increase in blood flow
4. Increase range of motion of contracted joints using heat and stretch techniques.

Neuromuscular Stimulation

1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain (Interferential and Pre-modulated waveforms)
2. Temporary relaxation of muscle spasm (all waveforms)
3. Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles (all waveforms)
4. Increase of blood flow in the treatment area (all waveforms)
5. Prevention or retardation of disuse atrophy in post-injury type conditions (all waveforms)
6. Muscle re-education (all waveforms)
7. Maintaining or increasing range of motion (all waveforms)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013192